92-1345

No.

Supreme Court, U.S.
FILED
FEB 8 1993
OFFICE OF THE CLERK

In The

Supreme Court of the United States

October Term, 1992

DR. ERICH PLATZER, DR. KARL WELTE and DR. ROLAND MERTELSMANN,

Petitioners,

vs.

SLOAN-KETTERING INSTITUTE FOR CANCER RESEARCH,

Respondent.

Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

PETITION FOR WRIT OF CERTIORARI

MARTIN R. GOLD
Counsel of Record
ROBERT P. MULVEY
GOLD, FARRELL & MARKS
Attorneys for Petitioners
Forty-One Madison Avenue
New York, New York 10010
(212) 481-1700

3230
Lutz Appellate Services, Inc.
(800) 3 APPEAL • (800) 5 APPEAL • (800) BRIEF 21

39 pp

QUESTION PRESENTED

When medical research funded by the United States Government at a nonprofit institution results in a critical new drug producing sales of over $600 million annually and generating enormous royalties for the institution, and when the funding agreements between the government agency and the institution fail to contain provisions that such royalties be shared with the inventors despite the requirement of 35 U.S.C. § 202(c) that:

> "Each funding agreement . . . shall contain appropriate provisions to effectuate . . . a requirement that the contractor share royalties with the inventor",

must the institution share such royalties with inventors on an appropriate and reasonable basis, or, as the lower courts held, may the institution adopt any policy it chooses to minimize the inventors' share, however unreasonable, and impose such policy upon inventors who did not agree to it and were not informed of it?

TABLE OF CONTENTS

	Page
Question Presented	i
Table of Contents	ii
Table of Citations	ii
Opinions Below	1
Statement of Jurisdiction	2
Constitutional Provision and Statute Involved	2
Statement of the Case	3
A. The Statute	3
B. The Facts	6
C. Prior Proceedings	9
Reasons for Granting the Writ	11
Conclusion	14

TABLE OF CITATIONS

Cases Cited:

Mazer v. Stein, 347 U.S. 201 (1954)	12
Miree v. DeKalb County, Georgia, 433 U.S. 25 (1977)	6 n.4

Contents

Page

Scheuer v. Rhodes, 416 U.S. 232 (1974) 6

United States Constitution Cited:

Article I, Section 8, Clause 8 ..... 2, 4

Statutes Cited:

28 U.S.C. § 1254(1) 2

28 U.S.C. § 1295(a)(1) 10 n.7

28 U.S.C. § 1331 ..... 9, 10

28 U.S.C. § 1338(a) 9, 10, 10 n.7

The University and Small Business Patent Procedures Act of 1980, (the "Bayh-Dole Act") Pub. L. 96-517, 94 Stat. 3020, as amended Pub. L. 98-620, 98 Stat. 3364-3366 ..... passim

35 U.S.C. § 200 11

35 U.S.C. § 202(c)(7)(B) 2, 3, 5, 9, 10, 13

35 U.S.C. § 202(c)(7)(C) 2, 3, 11

Legislative History Cited:

H.R. Rep. No. 1307, 96th Cong., 2d Sess., pt. 1 (1980), *reprinted in* 1980 U.S. Code Cong. & Admin. News 6460 (1980) 4, 4 n.2

Contents

Page

S. Rep. No. 480, 96th Cong., 1st Sess. (1979) 4, 4 n.3, 5, 12

Rules and Regulations Cited:

Federal Rule of Civil Procedure 12(b)(1) 10

Federal Rule of Civil Procedure 12(b)(6) 10

HHS Regulation, 46 F.R. 62548 (1981) 12

Other Authorities Cited:

Golde & Gasson, "Hormones That Stimulate The Growth of Blood Cells," *Scientific American*, (July 1988) p. 62 6

Washington Post, "Dividing The Royalty Pie", Health News p. 9, Nov. 17, 1992 7

APPENDIX

Appendix A — Judgment of the United States Court of Appeals for the Federal Circuit Filed November 10, 1992 ..... 1a

Appendix B — Memorandum Opinion and Order of the United States District Court for the Southern District of New York Filed March 4, 1992 ..... 3a

No.

In The

Supreme Court of the United States

October Term, 1992

DR. ERICH PLATZER, DR. KARL WELTE and DR. ROLAND MERTELSMANN,

Petitioners,

vs.

SLOAN-KETTERING INSTITUTE FOR CANCER RESEARCH,

Respondent.

Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

PETITION FOR WRIT OF CERTIORARI

OPINIONS BELOW

The opinion of the United States District Court, Southern District of New York, dismissing Petitioners' complaint, is reported at 787 F. Supp. 360 (S.D.N.Y. 1992). (A.3-20).[1]

1. References to the Appendix to this Petition are referred to herein as (A.__).

The decision of the United States Court of Appeals for the Federal Circuit, affirming without opinion, is reported at 1992 U.S. App. LEXIS 30528 (Nov. 10, 1992). (A.1-2).

STATEMENT OF JURISDICTION

The judgment of the United States Court of Appeals for the Federal Circuit was entered on November 10, 1992. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

CONSTITUTIONAL PROVISION AND STATUTE INVOLVED

Article I, Section 8, Clause 8 of the United States Constitution provides that Congress is empowered:

> To promote the progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.

Section 6(a) of the University and Small Business Patent Procedures Act of 1980 (the "Bayh-Dole Act"), Pub. L. 96-517, 94 Stat. 3020, as amended Pub. L. 98-620, 98 Stat. 3364-3366, 35 U.S.C. § 202(c), provides in pertinent part:

> Each funding agreement ... shall contain appropriate provisions to effectuate the following:
> (7) In the case of a nonprofit organization,
> * * *
> (B) a requirement that the contractor share royalties with the inventor;

> (C) . . . a requirement that the balance of any royalties or income earned by the contractor with respect to subject inventions, after payment of any expenses (including payments to inventors) incidental to the administration of subject inventions, be utilized for the support of scientific research or education.

STATEMENT OF THE CASE

A. The Statute

This case focuses on major legislation enacted by Congress to stimulate the economy by promoting scientific advancement and technological innovation. At this critical time when our economy is faltering, the lower courts have completely misconstrued and undermined the Bayh-Dole Act of 1980, which was intended to use government-funded research to provide incentives necessary to enhance our free-market economy. The decisions below eviscerate the explicit statutory requirement that inventors — the progenitors of technological advancement — must be appropriately compensated for their achievements.

After twelve years of congressional study, the Bayh-Dole Act was passed to effectuate major changes in the patent laws applicable to government-funded research. The dimension of the problem sought to be remedied by the legislation is described in the congressional reports accompanying the Act:

> The crisis in U.S. productivity and the governmental role in it has not gone unnoticed, ... In May of 1978 the President called for a major policy review of industrial innovation as

> the key to increased productivity in the United States.[2]
>
> * * *
>
> The Senate Select Committee on Small Business cited a study which attributed 45 percent of the Nation's economic growth from 1929 to 1969 to technological innovation.[3]

The statute provides significant financial incentives to inventors and institutions involved in government-funded research in order to encourage invention and its commercial application for the welfare of the public and the economy. For the first time, the Act provided for nonprofit institutions to issue exclusive commercial licenses for new inventions, and reap financial benefits from technological advances achieved in their laboratories, even though the research was entirely funded with government money.

The subject of this case, appropriate financial incentives to inventors, is in perfect accord with the Patent Clause of the Constitution, Article I, Section 8, Clause 8, which authorizes Congress:

> To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.

It is pursuant to this congressional power, focused squarely on

---

2. H.R. Rep. No. 1307, 96th Cong., 2d Sess., pt. 1 at 2 (1980), *reprinted in* 1980 U.S. Code Cong. & Admin. News 6460 at 6461.

3. S. Rep. No. 480, 96th Cong., 1st Sess. at 2 (1979).

inventors, that the Bayh-Dole Act was passed, and incorporated into the patent laws. Inventors' rights are explicitly contained in the statute; 35 U.S.C. § 202(c) provides, in pertinent part:

> Each funding agreement ... shall contain appropriate provisions to effectuate the following:
>
> * * *
>
> (7) In the case of a nonprofit organization,
>
> * * *
>
> (B) a requirement that the contractor share royalties with the inventor;

In keeping with this provision, the Senate Report accompanying the legislation states that the statute "gives special recognition to the equity of inventors, and requires that nonprofit organizations share royalties with them." S. Rep. No. 480 at p. 33.

The statute mandates that the inventors' share must be "appropriate," and government agencies funding research are required to ensure compliance; each government funding agreement with a private institution must contain a royalty-sharing provision which must be "appropriate ... to effectuate" the legislative purpose.

Nothing in the legislative history suggests that Congress intended what has occurred in this case — that a government-funded private institution could evade the statute by omitting the required royalty-sharing provision from its funding agreements, pay its inventors any amount it unilaterally chooses, and avoid administrative or judicial review. Such conduct, approved by the lower courts, does violence to the statutory scheme.

B. The Facts[4]

The three petitioners are distinguished research physicians who from 1982 to 1984 conducted medical research in New York City in the laboratories of defendant, Sloan-Kettering Institute for Cancer Research ("SKI"). Their research was funded by the government through the Department of Health and Human Services at virtually no cost to SKI. The funding agreements, however, do not comply with the Bayh-Dole Act; they do not contain any provision for the sharing of royalties with inventors. Petitioners' employment agreements also contain no royalty-sharing provisions, and SKI did not inform Petitioners of any policy concerning that subject.

The subject matter of Petitioners' enormously successful research was hemopoietins, the hormones which induce production of various kinds of blood cells in human beings. The medical research community has now come to recognize that these hormones "may effect a revolution in medicine as profound as the introduction of antibiotics half a century ago." (Golde & Gasson, "Hormones That Stimulate the Growth of Blood Cells," *Scientific American*, July 1988, p. 62).

Petitioners' specific research at SKI concerned a hormone known as granulocyte colony stimulating factor ("G-CSF"), which stimulates the production of neutrophils, which are white blood cells essential to the body's immune system. Petitioners' innovative research made it possible to produce G-CSF commercially.[5]

---

4. SKI did not dispute any of the facts asserted in the complaint. For purposes of the motion to dismiss, the appeal and this Petition, the allegations contained in the complaint, and all reasonable inferences therefrom, must be assumed to be true. *See, e.g., Miree v. DeKalb County, Georgia*, 433 U.S. 25, 27 n.2 (1977); *Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974).

5. Petitioner Dr. Erich Platzer was the progenitor of the research. In 1982, (Cont'd)

This critical drug is now, for the first time, available and regularly prescribed for use with chemotherapy for virtually all cancer patients. It materially reduces the deleterious side effects of such treatment and enables patients to tolerate larger therapeutic dosages. It will have many other significant medical applications for the prevention and treatment of neutropenia, including bone marrow transplants, burn treatment and concomitant AIDS therapy.

Once the therapeutic and financial benefits from Petitioners' discovery became apparent, SKI granted an exclusive license for commercial production of the drug to Amgen, Inc., a California-based pharmaceutical company which now markets it throughout the United States (under the brand name "Neupogen") and throughout much of the world.

The financial impact of Petitioners' invention is unprecedented. SKI did not dispute below that sales of G-CSF will be at least $600 million annually. As reported in a detailed Washington Post report discussing Petitioners' invention and the significance of this case, Neupogen "appears to be the richest royalty-producing invention ever to come out of a nonprofit institution." *Washington Post*, "Dividing The Royalty Pie," Health News p. 9 (Nov. 17, 1992).

In November 1990, SKI received from its exclusive licensee, Amgen, an initial payment of U.S. royalties of $50 million, and

---

(Cont'd)

he hypothesized that, by working in collaboration with Petitioner Dr. Karl Welte, he might be able to purify G-CSF for amino-acid sequencing. For the next two years, Dr. Platzer and Dr. Welte pursued their research together at SKI, often working in collaboration with Petitioner Dr. Roland Mertelsmann, and with Dr. Malcolm A.S. Moore and Dr. Janice Gabrilove. Drs. Moore and Gabrilove remain employed at SKI and have not joined in this lawsuit.

SKI will receive other enormous payments well into the future. SKI has virtually no expenses to pay from these funds because Petitioners' research was financed by the government.

At a time unknown to Petitioners, SKI unilaterally adopted a policy of distributing to inventors a portion of the annual gross proceeds derived from inventions and discoveries. Petitioners never agreed to this policy and were not informed of it until years after their research was completed and the impact of their accomplishment was evident. Under this purported policy, SKI chooses to pay inventors a total of 5% of gross proceeds derived from their inventions in excess of $300,000. (A.4-5). Moreover, SKI divides the percentage *pro rata* among the inventors. Thus, in this case, where there are five inventors, each was only paid $505,490 from the first $50 million received by SKI, or approximately 1%.

It is not disputed that the share of royalties paid to Petitioners by SKI is unreasonable when compared with allocations to inventors paid by other major research institutions. In order to amplify this undisputed allegation, Petitioners provided the lower courts with a compelling schedule of inventors' shares paid by 65 leading American institutions. Seventeen institutions pay 50% of royalties to inventors including, for example, all research campuses of the Universities of California and Texas and New York University. The Massachusetts Institute of Technology, Mount Sinai Medical Center (N.Y.) and Stanford University all pay 33 1/3% of royalties to inventors, which is the approximate average allocation among the 65 institutions surveyed, and which is approximately seven times the amount paid to inventors by SKI. Petitioners are aware of no institution which does not pay to inventors more than twice the share paid by SKI, and SKI has identified none.

C. Prior Proceedings

Petitioners filed suit on September 30, 1991, in United States District Court, Southern District of New York. The complaint alleges three federal claims, all derived from and dependent on the proper construction of the royalty-sharing requirement contained in 35 U.S.C. § 202(c) of the Bayh-Dole Act. Federal question jurisdiction is asserted under 28 U.S.C. § 1331, and patent law jurisdiction is invoked under 28 U.S.C. § 1338(a).

In their first claim, Petitioners asserted an implied private right of action under the statute, alleging that SKI had breached its statutorily-imposed obligation to share royalties with Petitioners.

In their second claim, Petitioners alleged that they are third-party beneficiaries of the congressionally-mandated contractual provision requiring SKI to share royalties reasonably with inventors. Petitioners argued, and SKI agreed, that although no royalty-sharing provision was actually included in the funding agreements, the requirement is incorporated by operation of law. Petitioners further argue that since the percentage of royalties to be paid to inventors was not included in the funding agreements or approved by a government agency to determine that it is "appropriate", the "appropriate" share must now be judicially determined. SKI argued that in the absence of a specific mandated ratio it was free to pay inventors any amount it chose, even if the share is unreasonable, inappropriate in light of the invention and not comparable to that paid by other institutions. Under SKI's contention, it could have satisfied the statutory requirement to share royalties with the inventors by giving each of the plaintiffs one dollar. The lower courts adopted SKI's argument.

In their third claim, Petitioners alleged that the required royalty-sharing provision is also incorporated by operation of law in their employment agreements with SKI. Again, SKI agreed that

the obligation to pay the inventors is a condition of Petitioners' employment agreements, but it argued that it could fulfill its duty by paying any amount it chose to pay.[6]

SKI moved to dismiss the complaint pursuant to Fed. R. Civ. P. 12(b)(1) and (6). The district court dismissed the first claim, finding no private right of action. It sustained federal "arising under" jurisdiction over Petitioners' second and third claims under 28 U.S.C. §§ 1331 and 1338(a) and then addressed the key issue — the meaning of 35 U.S.C. § 202(c)(7)(B). In a brief discussion, (A.17-19), the court found that providing financial incentives to inventors was not a purpose of the statute. It ruled that "Congress' concern was with the reinvesting of funds to further research, not with the private interests of individual inventors." (A.18). The district court concluded that Congress did not intend to establish any minimum share for inventors, and that the share paid to inventors need not be reasonable. The court therefore dismissed Petitioners' second and third claims. (A.19).

On November 10, 1992, a panel of the United States Court of Appeals for the Federal Circuit[7] affirmed the decision of the district court, without opinion. (A.1-2).

---

6. The fourth and fifth claims in the complaint are asserted on the basis of supplemental (formerly pendent) jurisdiction. They allege claims for breach of contract and unjust enrichment.

7. The Federal Circuit had exclusive jurisdiction over the appeal pursuant to 28 U.S.C. § 1295(a)(1) because jurisdiction in the district court was based "in whole or in part" under 28 U.S.C. § 1338(a) in a case involving the patent law.

REASONS FOR GRANTING THE WRIT

This is the first case to arise in any court requiring judicial interpretation of the Bayh-Dole Act. The Act was a major revision of the laws applicable to government-financed research. Its purpose was to promote and encourage technological advancement and economic development by creating significant financial incentives for inventors and private institutions. The lower courts' misreading of the Act obliterates the requirement that inventors, whose ingenuity furthers humanity and enriches their institutions, are entitled to share significantly in monetary rewards flowing from their work.

The lower courts' erroneous decisions were based upon 35 U.S.C. § 202(c)(7)(C) of the Act which requires that the institution's share of royalties must be used for scientific research or education. On the basis of this section the district court held: "Clearly Congress' concern was with the reinvesting of funds to further research, not with furthering the private interests of individual inventors." (A.18).

Nothing in the legislative history of the Bayh-Dole Act or the statute itself supports the lower courts' finding that the congressional "concern" behind the Act was to generate funds for further research and education. Although obviously desirable, this goal is quite incidental to, and much less important than, the clearly expressed purpose of promoting commercial technology and enhancing the economy. 35 U.S.C. § 200.

The advancement of technology is the goal of both the Act and the Patent Clause pursuant to which it was passed. Similarly, the means to this end, under both the Constitution and the Bayh-Dole Act, is the allowance of significant rewards to inventors.

The district court's conclusion that providing reasonable

financial incentives to inventors is not a significant aspect of the legislation not only undermines the purpose of the statute, but is thus also contrary to its constitutional underpinnings as construed by this Court. *See Mazer v. Stein*, 347 U.S. 201, 219 (1954) ("The economic philosophy behind the clause empowering Congress to grant patents and copyrights is the conviction that encouragement of individual effort by personal gain is the best way to advance public welfare through the talents of authors and inventors in 'Science and useful Arts'. Sacrificial days devoted to such creative activities deserve awards commensurate with the services rendered.").

In disregarding the intent of the statute to ensure that inventors are adequately compensated and receive incentives commensurate with their achievement, the lower courts ignored legislative history demonstrating that Congress enacted the Bayh-Dole Act based on its understanding that the prevailing practice among universities and research centers, when unfettered by regulation, was to share royalties with inventors in the range of 15% to 50%. However, prior to the passage of the Bayh-Dole Act, the Department of Health, Education and Welfare ("HEW") had imposed a 15% *ceiling* on royalty payments to inventors. Following the enactment of the Bayh-Dole Act, in December 1981, the Department of Health and Human Services ("HHS"), the successor agency to HEW, citing to the statement in S. Rep. No. 480 that the purpose of the Bayh-Dole Act was to give special recognition to inventors, "remove[d] the limitations on the share of royalty income that nonprofit organizations are permitted to share with their employee-inventors." 46 F.R. 62548 (1981).

Having accepted SKI's clearly erroneous argument that the Act's primary purpose was to maximize funds for further research, it is not surprising that the district court found that "allowing an

inventor to demand 50% of the royalties" would not further that purpose.[8] (A.13).

In fact, awarding Petitioners a reasonable share of royalties, which could be as much as the 50% share paid by many other institutions if the court so determines would indeed further the basic purpose of the statute. Consistent with congressional intent, such an award would attract talented young people to consider careers as research scientists. The once-in-a-lifetime sums Petitioners would receive, though considerably smaller than even the annual earnings of major athletes, entertainers and businessmen, would fairly compensate them for the benefit which their creativity has bestowed upon the world, and would induce others to follow their lead.[9]

---

8. Petitioners have never argued that any specific percentage of royalties must be shared with inventors under the Act, only that the share must be reasonable, or to use the equivalent word contained in the statute, "appropriate", and that the percentage should be judicially established, after considering the circumstances of the case.

9. This purpose was expressed to the United States Court of Appeals for the Federal Circuit by the Leukemia Society of America, Inc., in its motion for leave to file a brief as *amicus curiae* supporting Petitioners, as follows:

> The interest of The Leukemia Society in this appeal is to ensure that the royalty sharing provision of 35 U.S.C. § 202(c)(7)(B) is properly construed so that medical researchers are adequately financially compensated and thus optimally stimulated to continue to make medical breakthroughs, such as plaintiffs' invention, leading to more effective treatment of cancer and other diseases.

The Leukemia Society was denied leave to file its brief.

CONCLUSION

The present case offers an opportunity for this Court to consider and expound upon the purpose and intent of the Bayh-Dole Act, an important federal statute which this Court has not yet appraised, and to correct the lower courts' interpretation which undermines and eviscerates the purpose of the statute which is to stimulate technological development for the benefit of the economy and the public welfare.

Respectfully submitted,

MARTIN R. GOLD
Counsel of Record
ROBERT P. MULVEY
GOLD, FARRELL & MARKS
Attorneys for Petitioners
41 Madison Avenue
New York, New York 10010
(212) 481-1700

Dated: February 8, 1993

APPENDIX A — JUDGMENT OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT FILED NOVEMBER 10, 1992

Note: Pursuant to Fed. Cir. R. 47.8, this disposition is not citable as precedent. It is a public record. The disposition will appear in tables published periodically.

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

92-1280

DR. ERICH PLATZER, DR. KARL WELTE and DR. ROLAND MERTELSMANN,

Plaintiffs-Appellants,

v.

SLOAN-KETTERING INSTITUTE FOR CANCER RESEARCH,

Defendant-Appellee.

JUDGMENT

ON APPEAL from the UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

in CASE NO(S). 91-6578

This CAUSE having been considered, it is

Appendix A

ORDERED and ADJUDGED:

Per Curiam: (MAYER, CLEVENGER, and SCHALL, *Circuit Judges:*

AFFIRMED. See Fed. Cir. R. 36.

ENTERED BY ORDER OF THE COURT

DATED NOV 10 1992

s/ Francis X. Gindhart
Francis X. Gindhart, Clerk

APPENDIX B — MEMORANDUM OPINION AND ORDER OF THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK FILED MARCH 4, 1992

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

91 Civ. 6578 (JSM)

DR. ERICH PLATZER, DR. KARL WELTE and DR. ROLAND MERTELSMANN,

Plaintiffs,

-against-

SLOAN-KETTERING INSTITUTE FOR CANCER RESEARCH,

Defendant.

MEMORANDUM OPINION AND ORDER

JOHN S. MARTIN, JR., District Judge:

Doctors Erich Platzer, Karl Welte and Roland Mertelsmann commenced this action to recover a share of the royalties stemming from a discovery they made while in the employment of Sloan-Kettering Institute for Cancer Research ("Sloan-Kettering). Sloan-Kettering now moves to dismiss the complaint pursuant to Fed.R.Civ.P. 12(b)(1) and 12(b)(6). For the reasons contained herein, the motion to dismiss is granted in its entirety.

FACTUAL BACKGROUND

Sloan-Kettering is a not-for-profit corporation engaged in scientific research largely funded by the federal government.

Appendix B

The three plaintiffs are former employees of Sloan Kettering. While employed by Sloan Kettering, the plaintiffs were part of a team of five research physicians responsible for conducting research in the area of colony stimulating factors. This research resulted in a discovery: the purification of granulocyte colony stimulating factor ("G-CSF"), a natural substance which stimulates the production of white blood cells. White blood cells are vital to the body's immune system, and are often destroyed during the course of chemotherapy, resulting in life-threatening infections. By bolstering the body's production of white blood cells, G-CSF enables cancer patients to tolerate higher dosages of chemotherapeutic drugs. It may also play a role in the treatment of AIDS.

It is not disputed that Sloan-Kettering owns the rights to all discoveries and inventions made by Sloan-Kettering employees. This assignment of rights to Sloan-Kettering is both required under federal law and under Sloan-Kettering's own "Policy on Inventions, Patents, and Technology Transfer" (the "Patent Policy").

What is disputed is whether and to what extent Sloan-Kettering is required to share royalties with the Plaintiffs.

Two agreements are relevant here. Under Sloan-Kettering's Patent Policy, Sloan-Kettering is obligated to share royalties with inventors of *patented* discoveries on a sliding scale basis.[1] The

1. The Patent Policy provides:

> [the] annual gross proceeds from inventions or discoveries . . . shall be shared with the inventor(s) according to the rate table below.

(Cont'd)

Appendix B

Patent Policy expressly disclaims any obligation to share royalties with employees where the Patent office has denied a patent application.[2] However, the Patent Policy does allow for discretionary awards to inventors of unpatented inventions.

The second relevant agreement is the funding agreement entered into between Sloan-Kettering and the federal government. This Institutional Patent Agreement Governing Grants and Awards between Sloan-Kettering and the Department of Health, Education, and Welfare (the "IPA") applies to inventions arising out of government-funded research which are or may be patentable. The IPA as originally drafted allowed for the sharing of royalties with inventors up to a maximum of 15% of gross royalties. However, the terms of the IPA were modified by the 1980 Bayh-Dole Act. (Act of Dec. 12, 1980, Pub. L. 96-517, § 6(a), 94 Stat. 3019, codified at 35 U.S.C. § 200 *et seq.*). The Bayh-Dole Act grants non-profit organizations exclusive title to inventions developed through federal funding, and allows them to freely license such inventions for profit so long as such profit is used to

---

(Cont'd)

Annual Gross Proceeds	Inventor(s) Share %
$0 - $50,000	25%
$50,000 - $150,000	15%
$150,000 - $300,000	10%
Over $300,000	5%

2. The Patent Policy states:

> In the event that a patent application is denied, whether or not [Sloan-Kettering] intends to continue prosecution of the patent application or appeal the adverse decision, [Sloan-Kettering] shall not be obligated to pay a share of royalties received after the date of denial to the inventor(s).

fund additional scientific research. The statute at issue provides in relevant part:

> Each funding agreement with a . . . nonprofit organization shall contain appropriate provisions to effectuate the following:
>
> (b) a requirement that the contractor share royalties with the inventor.

35 U.S.C. § 202(c)(7)(B).

Even though its patent application for G-CSF was denied, Sloan-Kettering exercised its discretion to share the royalties from the discovery with the team of researchers responsible for the discovery. In accordance with the sliding scale of payments called for under the Patent Policy, Sloan-Kettering distributed a 5% share of the gross royalties[3] to the five scientists on the granucolyte team. Accordingly, each plaintiff received $505,490. Sloan-Kettering also notified the researchers that they would receive additional payments, based on the same formula, from any future royalties from domestic and foreign sales.

The plaintiffs allege that Sloan-Kettering's obligation to share royalties with inventors is non-discretionary by virtue of 35 U.S.C. § 202(c)(7)(B). Furthermore, they argue that even though § 202(c)(7)(B) does not designate any particular percentage or royalties which an institution is required to pay to inventors, the legislative history makes it clear that Congress intended the share to be reasonable and greater than 15%.

---

3. The gross royalty to Sloan-Kettering was an initial one-time balloon payment of $50 million from licensing the G-CSF to Amgen, Inc., a pharmaceutical company.

Appendix B

The Complaint sets forth five causes of action, the first three of which are based on the statute.

> (i) Plaintiffs assert an implied private right of action under the Statute, alleging that Sloan-Kettering has breached its statutorily imposed obligation to share royalties equally or equitably with inventors.
> (ii) Plaintiffs claim that they are entitled to a larger share on the ground that they are third-party beneficiaries of the IPA which, by operation of law, contains the mandated clause to share royalties with inventors.
> (iii) Plaintiffs claim that they are entitled to a larger share on the ground that the Statute created an implicit term of their employment agreement.
> (iv) and (v) Plaintiffs assert two state law claims, one under a contract theory and the other under an unjust enrichment theory.

Sloan-Kettering moves to dismiss the first three claims on the ground that the Court lacks subject matter jurisdiction over the claims in that they do not "arise under" the laws of the United States as required by 28 U.S.C. §§ 1331 and 1338(a). Additionally, Sloan-Kettering seeks dismissal of these claims on the ground that they do not state a cause of action in that no private right of action exists under 35 U.S.C. § 202(c)(7)(B). Once these claims are dismissed, Sloan-Kettering argues that the Court should decline to exercise its supplemental jurisdiction over the state law claims, or in the alternative should dismiss these claims for also failing to state a claim for which relief can be granted.

Appendix B

DISCUSSION

The First Cause of Action

For their first cause of action, Plaintiffs assert an implied private right of action under § 202(c)(7)(B), alleging that Sloan-Kettering breached its obligation to share royalties equitably with the inventors.

Sloan-Kettering seeks a dismissal of the first cause of action on the ground that this Court lacks subject matter jurisdiction and, in the alternative, on the ground that the first cause of action fails to state a claim for which relief may be granted.

Sloan-Kettering first argues that no private cause of action exists under § 202(c)(7)(B) and therefore the Court lacks subject matter jurisdiction and may not entertain the suit. This argument is clearly without merit. It is well settled that where a claim asserts an implied right of action under a statute, federal courts have the requisite federal jurisdiction to determine whether such a federal remedy exists. *Cherokee Express, Inc. v Cherokee Express*, 924 F.2d 603 (6th Cir. 1991); *Arroyo-Torres v. Ponce Federal Bank*, 918 F.2d 276 (1st Cir. 1990); *Till v. Unifirst Federal Sav. & Loan Ass'n*, 653 F.2d 152, 155 n.2 (5th Cir. 1981). *See also Bell v. Hood*, 327 U.S. 678, 90 L.Ed. 939, 66 S.Ct. 773 (1946).[4]

---

4. In *Bell v. Hood*, the Supreme Court stated in no uncertain terms that jurisdiction lies in actions that "seek recovery directly under the Constitution or laws of the United States." The Court was not bothered by the possibility that a private cause of action might not in fact exist.

> The reason for this is that the court must assume jurisdiction to decide whether the allegations state a cause of action on which the court can grant relief as well

(Cont'd)

Appendix B

Sloan-Kettering cites *Merrell Dow Pharmaceuticals, Inc. v. Thompson*, 478 U.S. 804, 106 S.Ct. 3229 (1986) for the proposition that where Congress has determined that there should be no private right of action for the violation of a federal statute, a claim based on that statute does not state a claim "arising under the Constitution, laws, or treaties of the United States" within the meaning of 28 U.S.C. § 1331. Sloan-Kettering reads this case too broadly. Specifically, Sloan-Kettering fails to take into consideration that *Merrell Dow* did not involve a direct implied right of action, but rather involved a state law action which required interpretation of a federal statute. The importance in this distinction can not be overemphasized. The Supreme Court stated, "This case does not pose a [direct] federal question . . . respondents do not allege that federal law creates any of the causes of action that they have

---

(Cont'd)

> as to determine issues of fact arising in the controversy. Jurisdiction, therefore, is not defeated as respondents seem to contend, by the possibility that the averments might fail to state a cause of action on which petitioners could actually recover. For it is well settled that the failure to state a proper cause of action calls for a judgment on the merits and not for a dismissal for want of jurisdiction. Whether the complaint states a cause of action for which relief could be granted is a question of law and just as issues of fact it must be decided after and not before the court has assumed jurisdiction over the controversy. If the court does later exercise its jurisdiction to determine that the allegations in the complaint do not state a ground for relief, then dismissal of the case would be on the merits, not for want of jurisdiction.

Bell v. Hood, 327 U.S. 678, 682, 66 S.Ct. 773, 776 (1946).

asserted." *Merrell Dow*, 478 U.S. at 809, 106 S.Ct. at 3233. As such, its holding was limited to state law claims alleging violations of federal statutes: "A complaint alleging a violation of *a federal statute as an element of a state cause of action*, when Congress has determined that there should be no private, federal cause of action for the violation, does not state a claim 'arising under the Constitution, laws, or treaties of the United States.' " *Merrell Dow*, 478 U.S. at 817, 106 S.Ct. at 3237 (emphasis added).[5]

Because the first claim is premised on the assertion that an implied private right of action exists under § 202(c)(7)(B), this claim arises under the laws of the United States and subject matter jurisdiction exists.

This conclusion, however, does not dispose of the issue. Rather, the private cause of action claim should nevertheless be dismissed pursuant to F.R.C.P 12 (b)(6) if the Court determines that the claim does not state a cause of action for which relief may

---

5. A few courts have interpreted *Merrell Dow* as standing for the proposition that subject matter jurisdiction is lacking for any claim that alleges a violation of a federal statute where no private right of action exists for that statute. *See, e.g., Angela Cummings, Inc. v. Purolator Courier Corp.*, 670 F. Supp. 92 (S.D.N.Y. 1987) ("A federal statute that does not create or imply private rights of action does not present a federal question pursuant to 28 U.S.C. § 1331"). These courts read *Merrell Dow* too broadly. Rather, *Merrell Dow*, by its holding, applies only to state law claims alleging violations of federal statutes. The cases relied on by Sloan-Kettering do not purport to hold otherwise. *See. e.g., Willy v. Coastal Corp.*, 855 F.2d 1160, 1168 (5th Cir. 1988) (existence of a private cause of action is "a necessary predicate to determining that the presence of a federal element in a state-created cause of action result[s] in that cause of action being one which ar[ises] under federal law"); *Utley v. Varian Assocs., Inc.*, 811 F.2d 1279, 1283 (9th Cir.) ("Under *Merrell Dow*, if a federal law does not provide a private right of action, then a state law action based on its violation perforce does not raise a 'substantial federal question' sufficient to confer federal-question jurisdiction."), *cert. denied*, 484 U.S. 824, 108 S.Ct. 89 (1987).

be granted. Thus, if Congress did not intend for a private cause of action to exist under the statute, the claim will be dismissed.[6]

In ascertaining whether a private cause of action exists under a federal statute, courts are to consider four factors: (1) whether plaintiff is part of the class for whose especial benefit the statute was passed; (2) whether the legislative history indicates a Congressional intent to confer a private right of action; (3) whether a federal cause of action would further the underlying purpose of the legislative scheme; and (4) whether the plaintiff's cause of action is a subject traditionally relegated to state law. *See Merrell Dow*, 478 U.S. at 810-11, 106 S.Ct at 3233; *California v. Sierra Club*, 451 U.S. 287, 293, 101 S.Ct. 1775, 1778 (1981); *Cannon v. University of Chicago*, 441 U.S. 677, 689-709, 99 S.Ct. 1946, 1953-64 (1979); *Cort v. Ash*, 422 U.S. 66, 78, 95 S.Ct. 2080, 2087 (1975).

The first factor to be considered is whether the plaintiff is a member of the class for whose "especial" benefit the statute was enacted. A review of the legislative history does not suggest that the Bayh-Dole Act was enacted for the benefit of research scientists. The Bayh-Dole Act was intended "to promote the utilization and commercialization of inventions made with Government support, to encourage the participation of smaller firms in the Government research and development process, and to promote increased cooperation and collaboration between the nonprofit and commercial sectors." 35 U.S.C. § 200 ("Policy and Objectives"). To such end, the intended beneficiaries of the Bayh-Dole Act are the institutions themselves and the government.

---

6. This two part approach to subject matter jurisdiction and claim sufficiency for implied right of actions is consistent with the approach suggested in *Bell v. Hood*. *See* Note 4 *supra*.

Furthermore, the language of § 202(c)(7)(B) typifies the statutory scheme in which federal courts have routinely refused to find an implied right of action. The statute here serves as a directive to organizations that receive federal funding. As such, the language is similar to the statute at issue in *Universities Research Ass'n v. Coutu*, 450 U.S. 754, 101 S.Ct. 1451 (1981). In *Coutu*, the Supreme Court declined to infer a private cause of action to employees under the Davis-Bacon Act, which obligated federal contractors to pay certain wages to employees.[7] The Court concluded that even though the language of the statute indicated an intent to benefit the class to which the plaintiff belonged, the language failed to indicate that "Congress intended that [the statute] be enforced through private litigation. Because "Congress, rather than drafting the legislation 'with an unmistakable focus on the benefited class,' instead . . . framed the statute simply as a general prohibition or a command to a federal agency," the Court refused to infer a private remedy. *Coutu*, 450 U.S. at 772, 101 S.Ct. at 1462 (quoting *Cannon v. University of Chicago*, 441 U.S. 677, 690-92, 99 S.Ct 1946, 1954-55 (1979)). *See also Rapid Transit Advocates v. Southern California Rapid Transit Dist.*, 752 F.2d 373, 377 (9th Cir. 1985) (no private right of action under a statute which focused on spending directives and conditions for government grants): *Osborn v. American Ass'n of Retired Persons*, 660 F.2d 740, 745 (9th Cir. 1981).

Similarly, the legislative history does not indicate and intent to create a private right of action. Indeed, the legislative history is

---

7. 40 U.S.C. § 276a(a) of the Davis-Bacon Act provided that the advertised specifications for every federal contract in excess of $2000 "for construction, alteration, and/or repair . . . of public buildings or public works of the United States . . . shall contain a provision stating the minimum wages to be paid various classes of laborers and mechanics which shall be based upon the wages that will be determined by the Secretary of Labor to be prevailing."

completely silent with regard to a private cause of action. As such, it is safe to assume that Congress did not intend for a private right of action to exist. *Touche Ross & Co. v. Redington*, 442 U.S. 560, 576, 99 S.Ct. 2479, 2489 (where legislative history is silent, "[t]he question whether Congress . . . intended to create a private right of action, has been definitely answered in the negative"). This conclusion is supported by the fact that elsewhere in the patent statutes, Congress did explicitly grant private causes of action. *See, e.g.*, 35 U.S.C § 281 (1988) (a "patentee shall have remedy by civil action for infringement of his patent"); 35 U.S.C. §§ 141-145 (1988) (applicant whose patent is rejected by the Patent Office on appeal may pursue his claim in the federal courts). The fact that elsewhere in the patent statutes private rights were expressly provided indicates that "when Congress wished to provide a private damage remedy, it knew how to do so and did so expressly." *Touche Ross*, 442 U.S. at 573, 99 S.Ct. at 2487. Likewise, that such a right was not created under § 202(c)(7)(B) suggests that no right was intended.

Nor would implication of such a right further the purpose of the statute. The Bayh-Dole Act was enacted to foster commercial development of government funded research. As such, the statute requires that royalties be funneled back into scientific research. See H.R. Rep. No. 1307, 96th Cong., 2d Sess., pt.1, at 5, 2 (1980), reprinted in 1980 U.S. Code Cong. & Adm. News 6460, 6464, 6461. A private right of action allowing an inventor to demand 50% of the royalties, as is the case here, would clearly frustrate this purpose rather than further it.

In light of the foregoing, the Court concludes that no private cause of action exists under § 202(c)(7)(B) of the Bayh-Dole Act. Accordingly, the first cause of action asserting an implied right must be dismissed for failing to state a claim for which relief can be granted.

Appendix B

The Second and Third Causes of Action

The Plaintiff's second and third claims are brought under third-party beneficiary and breach of contract theories. Both claims require interpretation of § 202(c)(7)(B). As with the first cause of action, Sloan-Kettering argues that dismissal is warranted because the Court lacks subject matter jurisdiction and because the cause of action fails to state a claim for which relief may be granted. These arguments will be considered in turn.

Sloan-Kettering cites *Merrell Dow* to support its position that the Court lacks subject matter jurisdiction for state-law claims alleging federal violations where no private right of action exists for the underlying federal statute. Specifically, Sloan-Kettering asserts that the second and third claims clearly fall under the category of cases considered in *Merrell Dow*. "[While] the vast majority of cases brought under the general federal-question jurisdiction of the federal courts are those in which federal law creates the cause of action . . . [we have] also noted that a case may arise under federal law 'where the vindication of a right under state law necessarily turn[s] on some construction of federal law.' " *Merrell Dow*, 478 U.S. at 808, 106 S.Ct. at 3232 (quoting *Franchise Tax Board*, 463 U.S. at 9, 103 S.Ct. at 2846).

As the Defendant reads *Merrell Dow*, the absence of a private right of action for an underlying federal statute where a state-law claim is asserted is dispositive. Sloan-Kettering argues that once the court has concluded that no private cause of action exists for the underlying federal violation, the court may not hear the claim unless independent jurisdictional grounds exist.

Once again, Sloan-Kettering reads *Merrell Dow* too broadly. Specifically, Sloan-Kettering attempts to extend the holding of

Merrell Dow, which involved a state law claim in which the alleged federal violation was peripheral,[8] to cases where the alleged violation is essential to the existence of the state-law claim.

That *Merrell Dow's* reach should not be so extended is suggested in the language of the opinion itself. The Court left undisturbed the holding of *Franchise Tax Board*, that federal question jurisdiction is "appropriate when 'it appears that some substantial, disputed question of federal law is a necessary element of the well-pleaded state claims.' " *Merrell Dow*, 478 U.S. at 813, 106 S.Ct. at 3234 (quoting *Franchise Tax Board*, 463 U.S. at 13, 103 S.Ct. at 2848). Leaving intact "arising under" jurisdiction to determine substantial questions of federal law, the Court held that the "*mere presence* of a federal issue in a state cause of action does not automatically confer federal question jurisdiction." *Merrell Dow*, 478 U.S. at 813, 106 S.Ct. at 3234 (emphasis added). As such, the Court emphasized the need to evaluate "the nature of the federal issue, *Merrell Dow*, 478 U.S. at 814 n.12, 106 S.Ct. 3235 n.12, and the "need for careful judgments about the exercise of federal judicial power in . . . area[s] of uncertain jurisdiction." *Merrell Dow*, 478 U.S. at 814, 106 S.Ct. at 3235.[9]

---

8. *Merrell Dow* involved a products liability claim that children were born with deformities as a result of the injection of Bendectin. Of the six counts in the complaint, only one implicated federal law. That claim asserted, in part, that the drug was misbranded in violation of the Federal Food, Drug and Cosmetic Act ("FDCA") and that the violation of the FDCA constituted "a rebuttable presumption of negligence." *Merrell Dow*, 478 U.S. at 805-06, 106 S.Ct. at 3230-31.

9. Emphasizing the nature of the federal issue within the state-law claim, the Court went on to cite with approval *Textile Workers Union v. Lincoln Mills of Alabama*, 353 U.S. 448, 470, 77 S.Ct. 912, 928 (1957) (Frankfurter, J., dissenting) (defining the inquiry as "the degree to which federal law must be in the forefront of the case and not collateral, peripheral or remote"). *Merrell Dow*, 478 U.S. at 813 n. 11, 106 S.Ct. at 3234 n. 11.

Thus, even where no private right of action exists for the underlying federal issue, if the nature of the federal issue is sufficiently substantial, subject matter jurisdiction may still exist. *West 14th Street Commercial Corp. v. 5 West 14th Owners Corp.*, 815F.2d 188 (2d Cir.), *cert. denied*, 484 U.S. 850, 108 S.Ct. 151 (1987).[10] *See also Milan Express Co. v. Western Surety*, 886 F.2d 783(6th Cir. 1989) (distinguishing *Merrell Dow* and holding that the lack of a private right of action did not preclude a finding that subject matter jurisdiction existed); *Smith v. Industrial Valley Title Insurance Co.*, No. 90-2132 (E.D. Pa. Aug. 2, 1990) (LEXIS, Genfed library, Dist file) (interpreting the "delphic" *Merrell Dow* opinion as being limited to cases where the federal element is "merely present" rather than substantial); *New York v. Rapgal Assocs.*, 703 F. Supp. 284 (S.D.N.Y. 1989) (finding that the

---

10. The language used by the Second Circuit to distinguish *Merrell Dow* is equaly applicable here:

> [A]ssuming that plaintiffs have no private right of action under [the federal statute], we conclude that the federal element in the plaintiff's state cause of action would still be sufficiently substantial to confer arising under jurisdiction. In *Merrell Dow* the federal statute was merely incorporated by reference as a standard of conduct in a state negligence claim. Here, the situation is quite different. In construing the [the federal statute in question] in a state cause of action, the federal issue is decisive because upon the Act's construction the vindication of rights and definition of relationships created by federal law depends .... In light of this qualitative difference, the federal ingredient in plaintiffs' complaint in this case is sufficiently substantial to confer the arising under jurisdiction.

West 14th Street Commercial Corp., 815 F.2d at 196 (citations omitted).

existence of a private right was immaterial where claims were derived from federal law and resolution of the dispute turned on construction of federal law).

Here, the federal issues in the Plaintiffs' second and third claims are sufficiently substantial to confer "arising under" jurisdiction.[11] Indeed, the federal issue is essential to Plaintiffs' breach of contract and third-party beneficiary claims. As such, a substantial federal issue exists and subject matter jurisdiction is proper.

Sloan-Kettering next argues that dismissal of the second and third causes of action is warranted on the ground that these causes of action fail to state a claim for which relief can be granted.

In determining whether Plaintiffs' have stated a claim upon which relief may be granted, the Court must first turn to the

---

11. In reaching this conclusion, the Court is doing no more than following the admonition of Justice Cardozo in *Gully v. First Nat'l Bank*, 299 U.S. 109, 57 S.Ct. 96 (1936). Discussing the boundaries of arising under jurisdiction, Justice Cardozo stated:

> What is needed is something of that common sense accommodation of judgment to kaleidoscopic situations which characterizes the law in its treatment of problems of causation . . . . a selective process which picks the substantial causes out of the web and lays the other ones aside . . . . To set bounds to the pursuit, the courts have formulated the distinction between controversies that are basic and those that are collateral, between disputes that are necessary and those that are merely possible. We shall be lost in the maze if we put that compass by.

Gully v. First Nat'l Bank, 299 U.S. at 117-18, 57 S.Ct. at 99-100.

language of the statute. The language of § 202(c)(7)(B) is clear:

> Each funding agreement with a . . . non profit organization shall contain appropriate provisions to effectuate the following . . . (7)(B) a requirement that the contractor share royalties with the inventor.

35 U.S.C. § 202(c)(7)(B).

The Plaintiffs' second and third claims are premised on the argument that § 202(c)(7)(B) contains an implicit requirement that institutions share a specific percentage of their royalties with inventors and scientists. However, nothing in the language suggests that the share should be a specified ratio. Nor does the definition of "share" suggest that a particular ratio was intended. In common usage, the unmodified verb "share" simply means "to have a share: take part." New Webster's Dictionary of the English Language 2087 (3rd ed. 1981). Black's Law Dictionary (5th ed. 1979) specifically contrasts the unmodified word "share," which it defines as "[t]o partake; enjoy with others have a portion of," with the term "share and share alike," which is defined as referring to "equal shares or proportions." In short, the plain language of the statute does not yield the interpretation that the Plaintiff's ask us to make, that a particular ratio of sharing was intended.

Nor does the legislative history suggest a ratio for sharing. Congress enacted the Bayh-Dole Act "to promote the utilization and commercialization of inventions made with government support." 35 U.S.C. § 200 ("Policy and Objective" of Bayh-Dole Act). To further this aim, the Bayh-Dole Act provides that non-profit institutions receiving government funding must reinvest royalties from research into additional research. 35 U.S.C.

§ 202(c)(7)(C). Clearly Congress' concern was with the reinvesting of funds to further research, not with furthering the private interests of individual inventors. The provision that non-profit institutions share royalties was included merely to ensure that inventors were provided with an adequate incentive to engage in scientific research. Furthermore, that any sharing ratio should be left to the supply and demand of the market is suggested by Congress' refusal to determine a particular share: "It is not intended that Federal agencies establish sharing ratios." S. Rep. No. 480, 96th Cong., 1st Sess. at 33 (1979).

The regulations established by the executive agency charged with administering § 202 support the conclusion that no particular share or minimum share was intended by Congress. Specifically, the agency has expressly declined to establish any "minimum sharing formula" on the ground that to do so would be "inconsistent with the legislative intent as manifest on p. 33 of the Senate Report 96-480." 47 Fed. Ref. 7556 at 9, Feb. 19, 1982. The agency has noted that "[t]he intent is that non-profit organizations share . . . in accordance with their usual policies."

In sum, a review of the language of the statute, its legislative history, and subsequent agency regulations fails to suggest that Congress intended that institutions follow a federally imposed sharing ratio or minimum share. As plaintiff's second and third claims are premised on such a minimum share, the Court must conclude that these actions fail to state a claim for which relief can be granted. Accordingly, the second and third claims are dismissed.

The State-Law Claims

With the federal claims dismissed, the only remaining claims are state law claims under contract and unjust enrichment theories.

Appendix B

In accordance with 28 U.S.C. § 1367(c)(3), the Court declines to exercise its supplemental jurisdiction over plaintiff's remaining claims.

Accordingly, the complaint is dismissed in its entirety

SO ORDERED.

Dated: March 2, 1992

s/ John S. Martin
JOHN S. MARTIN, JR., U.S.D.J.

Supreme Court, U.S.
FILED
MAR 5 1993
OFFICE OF THE CLERK

No. 92-1345

IN THE

Supreme Court of the United States

October Term, 1992

DR. ERICH PLATZER, DR. KARL WELTE
and DR. ROLAND MERTELSMANN,

Petitioners,

v.

SLOAN-KETTERING INSTITUTE FOR
CANCER RESEARCH,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF IN OPPOSITION

STEVEN B. ROSENFELD
1285 Avenue of the Americas
New York, New York 10019-6064
(212) 373-3000
Counsel of Record for Respondent

Of Counsel:

CATHERINE J. ROSS
KATHLEEN M. WALKER

PAUL, WEISS, RIFKIND, WHARTON & GARRISON

COUNTERSTATEMENT OF THE QUESTION PRESENTED

Whether the United States Court of Appeals for the Federal Circuit and the United States District Court for the Southern District of New York properly held that 35 U.S.C. § 202(c)(7)(B) was not intended to circumvent free market forces either by establishing minimum royalty sharing ratios for inventors or by empowering courts or juries to determine such inventors' share of royalties?

STATEMENT PURSUANT TO RULE 29.1

Respondent Sloan-Kettering Institute For Cancer Research states that it has no parent companies and also has no subsidiaries that are not wholly owned

TABLE OF CONTENTS

Page

COUNTERSTATEMENT OF THE QUESTION PRESENTED i

STATEMENT PURSUANT TO RULE 29.1 ii

TABLE OF AUTHORITIES iv

COUNTERSTATEMENT OF THE CASE 1

REASONS FOR DENYING THE WRIT 4

THERE ARE NO SPECIAL OR IMPORTANT REASONS FOR REVIEW 4

THE DISTRICT COURT FULLY CONSIDERED AND CORRECTLY DECIDED THE ISSUE, AND THE COURT OF APPEALS PROPERLY AFFIRMED 5

A. The Statutory Language 5

B. The Legislative History 7

CONCLUSION 10

TABLE OF AUTHORITIES

CASES **PAGE**

Arizona v. *Mauro*,
481 U.S. 520 (1987) 4

Beam v. *IPCO Corp.*,
838 F.2d 242 (7th Cir. 1988) 3

Blue Chip Stamps v. *Manor Drug Stores*,
421 U.S. 723 (1975) 5

Gilliard v. *Mississippi*,
464 U.S. 867 (1983) 4

I.N.S. v. *Cardoza-Fonseca*,
480 U.S. 421 (1987) 7

Marks v. *United States*,
430 U.S. 188 (1977) 4

Massachusetts Trustees of E. Gas and Fuel Assocs. v. *United States*,
377 U.S. 235 (1964) 4

McCray v. *New York*,
461 U.S. 961 (1983) 4

Shapiro v. *United States*,
335 U.S. 1 (1948) 9

Stein v. *United Artists Corp.*,
691 F.2d 885 (9th Cir. 1982) 3

United States v. *James*,
478 U.S. 597 (1986) 5

STATUTES AND RULES **PAGE**

7 U.S.C. § 329 6

10 U.S.C. § 1434 6

15 U.S.C. § 4224 (a)(5)(A) 6

16 U.S.C.
§ 1103 6
§ 839d(m) 6

20 U.S.C. § 959 6

22 U.S.C. § 2453(c) 6

35 U.S.C.
§ 202(a) 6
§ 202(c) 7
§ 202(c)(1) 6
§ 202(c)(3) 6
§ 202(c)(7)(B) . . . . . passim
§ 202(c)(7)(C) 8,9
§ 202(c)(7)(D) 6
§ 202(c)(8) 6
§ 203 7
§ 204 7

43 U.S.C. § 617d(d) (1988) 6

Pub. Law No. 98-115 § 806,
97 Stat. 786 (1983) 6

37 C.F.R. § 401.14(k) 9

46 Fed. Reg. 62548 (1981) 9

STATUTES AND RULES **PAGE**

Sup. Ct. R.
10.1(a) 4
10.1(c) 4
15 2

LEGISLATIVE MATERIAL

H.R. Rep. No. 1307, 96th Cong.,
2d Sess., pt. 1 (1980),
reprinted in 1980 U.S. Code Cong.
& Admin. News 6460 ("House Report") 8

S. Rep. No. 480, 96th Cong.,
1st Sess. (1979) ("Senate Report") 8,9

OTHER AUTHORITIES

Black's Law Dictionary (5th ed. 1979) 5,6

New Webster's Dictionary of the
English Language (3d ed. 1981) 5

No. 92-1345

IN THE
Supreme Court of the United States
October Term, 1992

DR. ERICH PLATZER, DR. KARL WELTE
and DR. ROLAND MERTELSMANN,

Petitioners,

v.

SLOAN-KETTERING INSTITUTE FOR
CANCER RESEARCH,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF IN OPPOSITION

COUNTERSTATEMENT OF THE CASE

Although petitioners acknowledge that their federal claims are "all derived from and dependent on" one phrase in a statute enacted over twelve years ago (P. 9),[1/] they admit that no court has even been called upon to construe that statute prior to this case (P. 11). On its face, therefore, the petition presents no questions of law that recur with any frequency, much less any on which the lower courts are in conflict. Accordingly, the decision of the United States District Court for the Southern District of New York, which was unanimously affirmed without opinion by the United States Court of Appeals for the Federal Circuit, presents no issues worthy of this Court's review.

[1/] Citations to "P. __" refer to pages of the Petition for Writ of Certiorari.

The basic facts material to this petition are simple and substantially undisputed. However, petitioners omit certain critical facts alleged in their own complaint, distort the holdings of the district court, and rely upon facts which were not properly part of the record below. Since these misstatements may "have a bearing on the question of what issues would properly be before the Court if certiorari were granted" (Sup. Ct. R. 15), we address them briefly here.

Petitioners frame both the "question presented" and their basic argument under 35 U.S.C. § 202(c)(7)(B), on the premise that the research funding agreement between the respondent Sloan-Kettering Institute for Cancer Research ("Sloan-Kettering") and the federal government does not contain any provision for the sharing of royalties (P. i, 6). This supposed omission, petitioners argue, leaves respondent free to "pay its inventors any amount it unilaterally chooses, and avoid administrative or judicial review" (P. 5). This argument simply contradicts what is alleged in petitioners' own complaint, despite their express recognition that "the allegations contained in the complaint . . . must be assumed to be true" (P. 6). The complaint alleges that all funding agreements between Sloan-Kettering and the federal government *did* include, either expressly or by operation of law, the requirement that royalties be shared with inventors (Cmplt. ¶¶ 28, 41, 45 and 49).[2/] Since those funding agreements were between Sloan-Kettering and a federal agency, they obviously did not escape "administrative . . . review" (P. 5). Petitioners thus ignore the district court's unassailable conclusion that the "executive agency charged with administering" the Bayh-Dole Act "has expressly declined to establish any 'minimum sharing formula' on the ground that to do so would be 'inconsistent with the legislative intent'" (A. 19a).[3/]

In this unique case, the enormous commercial potential of G-CSF created a royalty stream that vastly exceeded the top range

---

[2/] The Complaint filed in the United States District Court for the Southern District of New York, dated September 30, 1991, is annexed hereto as Appendix A (hereafter, "Cmplt.").

[3/] Citations to "A. __" refer to pages of the Appendix to the Petition for Writ of Certiorari.

of the sliding scale in Sloan-Kettering's Patent Policy, so that the *more than $2.5 million* paid in 1990 to the five inventors as a group came to 5.05% of the gross 1990 royalties—still, by any standard, a handsome amount and a more than adequate incentive to salaried research scientists.[4] Nevertheless, petitioners seek to portray these payments as unreasonable by referring to alleged facts *not* contained in their complaint, but rather annexed in their own attorney's affidavit, improperly submitted on the motion to dismiss (P. 8). While petitioners continue to trumpet their counsel's affidavit as a "compelling schedule" (P. 8), the fact is that its hearsay comparison of Sloan-Kettering's Patent Policy to alleged royalty distribution policies at other institutions played no part whatever in the lower courts' rulings, is irrelevant to the issue of statutory construction on which those courts ruled, and should properly be ignored by this Court as well. *Beam* v. *IPCO Corp.*, 838 F.2d 242, 244 (7th Cir. 1988); *Stein* v. *United Artists Corp.*, 691 F.2d 885, 889 (9th Cir. 1982).[5]

---

[4] Sloan-Kettering shared the G-CSF royalties with the five inventors by distributing over $2.5 million, calculated according to the sliding scale formula in Sloan-Kettering's "Policy on Inventions, Patents, and Technology Transfer," which gave the inventors *25%* of the first $50,000 in gross royalties received by Sloan-Kettering, *15%* of the next $100,000 and *10%* of the next $150,000, plus *5%* of the remainder up to $50 million (A. 5a; Cmplt. ¶ 31). Sloan-Kettering also informed petitioners that they would receive further payments from any future royalties based on the same formula (A. 6a).

[5] Some of the petitioners' other statement of facts are likewise based upon material beyond the allegations of the complaint. This includes assertions concerning petitioners' employment agreements (P. 6); Sloan-Kettering's alleged lack of financial contribution to the research (*id.*); reference to an *amicus curiae* brief which the Court of Appeals specifically denied leave to file (P. 12 n.9); and an article published in the *Washington Post* after the Court of Appeals affirmed the district court decision (P. 7).

REASONS FOR DENYING THE WRIT

I. THERE ARE NO SPECIAL OR IMPORTANT REASONS FOR REVIEW

In considering this petition, the Court need not even reach the merits of the issue presented, because it is not one which is appropriate for review under any of this Court's established criteria.

Petitioners admit that "[t]his is the first case to arise in *any* court requiring judicial interpretation of the Bayh-Dole Act" (P. 11; *emphasis added*). The fact that only one such case has been filed in the twelve years since the Bayh-Dole Act became law demonstrates by itself that the question petitioners present is not ripe for this Court's attention. There has been no development in the lower courts that would even begin to suggest that the issue is likely to arise again—much less that it will be frequently litigated. *See e.g.*, *Massachusetts Trustees of E. Gas and Fuel Assocs.* v. *United States*, 377 U.S. 235, 237 (1964).

Even if the issue were perceived to be one of broad importance, as petitioners insist, this Court's usual practice is to postpone consideration until more than one case has enabled lower courts to consider the question and suggest solutions. *See*, *e.g.*, *Gilliard* v. *Mississippi*, 464 U.S. 867, 869 (1983) (Marshall, J., dissenting from denial of certiorari). Moreover, since this is a case of first impression, there is concededly "no conflict of decision within the federal system." *McCray* v. *New York*, 461 U.S. 961, 963 (1983); *see also* Sup. Ct. R. 10.1(a). Finally, petitioners do not even suggest that the decisions below represent a significant departure "from the accepted or usual course of judicial proceedings" (Sup. Ct. R. 10.1(a); *see also Marks* v. *United States*, 430 U.S. 188, 189 (1977)), or that they "conflict with applicable decisions of this Court" (Sup. Ct. R. 10.1(c); *see also Arizona* v. *Mauro*, 481 U.S. 520, 525 (1987)).

In sum, other than their self-serving assertion that the question is important, petitioners cannot fit this case within any of the established criteria for granting a writ of certiorari. Moreover, as shown below, the decisions below were sound.

II. THE DISTRICT COURT FULLY CONSIDERED AND CORRECTLY DECIDED THE ISSUE, AND THE COURT OF APPEALS PROPERLY AFFIRMED

The district court made two clear and simple holdings—(1) that "no private cause of action exists under § 202(c)(7)(B) of the Bayh-Dole Act" (A. 13a) and (2) that "the language of the statute, its legislative history, and subsequent agency regulations fail[] to suggest that Congress intended that institutions follow a federally imposed sharing ratio or minimum share" (A. 19a). The petition apparently does not seek review of the first holding, and its challenge to the second is based on an incomplete and misleading presentation of both the statutory language and the legislative history.

A. The Statutory Language

"The starting point in statutory interpretation is 'the language [of the statute] itself,'" based on the ordinary understanding of the words chosen by Congress. *United States* v. *James*, 478 U.S. 597, 604 (1986), *quoting Blue Chip Stamps* v. *Manor Drug Stores*, 421 U.S. 723, 756 (1975) (Powell, J., concurring). The statute upon which plaintiffs premise all of their claims requires *only* that "[e]ach funding agreement with a . . . non-profit organization shall contain appropriate provisions" requiring, among *numerous* other things, that "the contractor share royalties with the inventor." 35 U.S.C. § 202(c)(7)(B) (1988). The words Congress chose clearly establish no formulas or guidelines concerning the amount of royalties to be paid to inventors. They merely impose an obligation *on federal granting agencies* to ensure that their funding agreements with nonprofit institutions include *some* provision for sharing royalties with individual inventors. The complaint alleges that Sloan-Kettering's funding agreements *do* contain such provisions (*see* p. 2 *supra*) and Sloan-Kettering has unquestionably complied with its contractual obligation by paying more than $505,000 to each inventor, with more to come.

Nothing on the face of the statute indicates that more is required. As the district court noted, "in common usage, the unmodified verb share means simply 'to have a share: take part.'" (A. 18a, *citing* New Webster's Dictionary of the English Language 2087 (3d ed. 1981)). Indeed, Black's Law Dictionary (5th ed.

1979) specifically *contrasts* the unmodified word "share," which it defines as "[t]o partake; enjoy with others; have a portion of," with the term "share and share alike," which is defined as referring to "*equal* shares or proportions." *Id.* That Congress used the unmodified verb advisedly in this instance is clear from the fact that, when Congress so intends, it has regularly specified that shares be equal.[9]

Unable to find anything helpful in the language Congress actually used in section 202(c)(7)(B), petitioners try to engraft an implied provision that the inventor's share "must be reasonable" (P. 13 n.8), and a corollary that what is "reasonable" in any given circumstance must be determined by courts and juries (P. 9). But this statute does not contain any express requirement that the royalty-sharing be "reasonable" or that it meet any equivalent standard. In sharp contrast, where Congress has intended in other contexts to require someone to pay a "reasonable share," it has expressly so provided in the statutory language.[7] More to the point, Congress used the word "reasonable" *seven times* in section 202—*the very statutory provision before this Court!*[8] But it

---

[9] *See, e.g.*, 7 U.S.C. § 329 (1988) (sums appropriated to be distributed to the states and territories "in equal shares"); 10 U.S.C. § 1434 (1988) (annuities payable to surviving children "in equal shares"); 16 U.S.C. § 1103 (1988) ("equal shares" of revenues to United States and Canada); 20 U.S.C. § 959 (1988) (donations to be distributed "in equal shares" to eligible federal agencies).

[7] *See, e.g.*, Pub. Law No. 98-115 § 806, 97 Stat. 786 (1983) (requiring that a "reasonable share" of architect/engineer contracts be set aside for small businesses, and expressly providing how it is to be determined); 22 U.S.C. § 2453(c) (1988) ("reasonable share" of cost of cultural exchange programs to be paid by the government); 43 U.S.C. § 617d(d) (1988) (requiring payment by agency using energy transmission line of "a reasonable share of the cost of construction, operation and maintenance"); 15 U.S.C. § 4224(a)(5)(A)(1988) (contractors must pay "a reasonable and proportionate share" of costs for all civilian government property they use); 16 U.S.C. § 839d(m) (1988) (federal power system must offer "a reasonable share" of resources to each regional utility).

[8] *See* 35 U.S.C. § 202(a) ("a reasonable time"); § 202(c)(1) ("a reasonable time"); § 202(c)(3) ("within reasonable times"); § 202(c)(7)(D) ("a reasonable inquiry"); and § 202(c)(8) (referring to "terms reasonable under the (continued...)

noticeably did not use that term, or any synonym, to modify the word "share" in section 202(c)(7)(B). The inescapable conclusion is that it did not intend to impose such a standard.

Petitioners' last-ditch effort is to seize upon the word "appropriate" in the introductory sentence of section 202(c), and argue that this adjective was (1) meant to modify "share" (P. 5) and (2) used to mean the "equivalent" of "reasonable" (P. 13 n.8). Neither argument has the slightest contextual support in the statute. First, the word "appropriate" clearly modifies "provisions"—i.e., the list of terms which are to be included in the funding agreement—not the word "share" as petitioners assert. Indeed, seven paragraphs and approximately 800 words separate the word "appropriate" from the word "share" in section 202(c). Second, construing "appropriate" as the "equivalent" of "reasonable" would lead to an absurd result. Could Congress really have intended that *each* of the twelve mandated provisions in funding agreements be "reasonable"—particularly when it used that precise word seven separate times in some, but not all, of the subsections enunciating those provisions? Congress could not have intended to write such a confusing statute—and it did not.

B. The Legislative History

With statutory language as clear and unambiguous as this, resort to the legislative history should hardly be necessary. But it bears noting that petitioners' presentation is incomplete and misleading.

Because the plain language of the statute does not specify any formula for determining the inventor's share of royalties, the district court properly looked to the legislative history only to determine whether it contains any clear expression of congressional intent sufficient to overcome the strong presumption that "Congress expresses its intent through the language it chooses." *I.N.S.* v. *Cardoza-Fonseca*, 480 U.S. 421, 432 n.12 (1987). In this instance, far from conflicting with the plain language, the legislative history adds compelling support to the view that Congress *never intended*

[9/](...continued)
circumstances" and "reasonable . . . efforts" contained in §§ 203 and 204 respectively).

to impose any specific sharing formula—much less to require that nonprofit institutions share royalties "reasonably" with inventors on terms to be determined by juries. Indeed, it demonstrates that Congress expressly *declined* to establish sharing ratios.

Seizing myopically on the fact that some royalty-sharing with inventors was contemplated, petitioners lose sight of the central purpose of the Bayh-Dole Act as a whole. Congress enacted the Bayh-Dole Act in 1980 because it was concerned about mounting evidence that the United States was falling behind in the development and commercial exploitation of patentable inventions, even as the federal government assumed a greater role in supporting basic scientific research. S. Rep. No. 480, 96th Cong., 1st Sess. (1979) at 1 ("Senate Report"); H.R. Rep. No. 1307, 96th Cong., 2d Sess., pt. 1 (1980) at 2, *reprinted in* 1980 U.S. Code Cong. & Admin. News 6460 ("House Report"). With a view to easing the government's financial burden, Congress acted "to promote the utilization and commercialization of inventions made with Government support . . . and *stimulate a greater return* on the billions of dollars spent each year by the government *on its research and development programs*." Senate Report at 3 (emphasis added); *see also* House Report at 2.

To that end, the statute sought to ensure that nonprofit institutions would contribute the royalties resulting from government-sponsored research to support further scientific research. House Report at 5; Senate Report at 30; *see also* 35 U.S.C. § 202(c)(7)(C) (1988). The legislative history thus emphasizes that neither nonprofit institutions nor individual inventors should receive "windfall profits" from federally-funded inventions. Senate Report at 18, quoting the Draft Report on Patent Policy, Advisory Subcommittee on Patent and Information Policy of the Advisory Committee on Industrial Innovation (1978); *see also id.* at 30. However, Congress received testimony suggesting that allotting *some* royalty share for inventors would serve as an incentive for scientists and academics to *identify patentable discoveries* and *remain involved in the time-consuming paperwork* necessary to obtain a patent. Surely, the more than half a million dollars each petitioner here has received (with more to come) is, by any definition, "significant financial incentive[]" (P. 4) for researchers to cooperate in patenting and developing their discoveries.

The only snippet of legislative history cited by petitioners in support of their argument (P. 5) is one sentence contained in the 39-page Senate Report. But the paragraph in which that snippet is contained reads in full:

> Section 202(c)(7)(C), gives special recognition to the equity of inventors, and requires that nonprofit organizations share royalties with them. *It is not intended that Federal agencies establish sharing ratios*. Senate Report at 33 (emphasis added).

The very next section of the Senate Report reiterates that the statute "requires nonprofit organizations to use the net proceeds of their licensing efforts to further scientific research and education." Senate Report at 33.

The Senate Report thus expressly *repudiates* the notion that the statute imposes any particular formula for sharing, or even authorizes administrative agencies to do so. Had the administrative agency charged with enforcement of the Bayh-Dole Act interpreted the statute as mandating that institutions share a minimum (or even "reasonable") amount of royalties with inventors, it could easily have so provided. Instead, the Department of Health and Human Services ("HHS") expressly ruled that Congress did *not* authorize the executive branch to establish any specific royalty-sharing formulas. 46 Fed. Reg. 62548 (1981). HHS simply reverted to the statutory language, calling for contractual terms providing that the "contractor will share royalties collected on a subject invention with the inventor." 37 C.F.R. § 401.14(k) (1991).

Petitioners are therefore wrong when they tell this Court that support of on-going scientific research was only an "incidental" effect of the Bayh-Dole Act (P. 11). The district court's conclusion that "Congress' concern was with the reinvesting of funds to further research, not with furthering the private interests of individual inventors" (A. 19a) is amply supported by the legislative history. As the district court observed (A. 13a), allowing juries to award inventors up to 50% of royalties, after costly litigation and trial, would clearly frustrate, rather than further, that congressional intent. *Cf. Shapiro* v. *United States*, 335 U.S. 1, 31 (1948) (courts should adopt statutory construction "which

effectuates rather than frustrates the major purpose" of the legislation.)

In sum, nothing in *this* statute, its legislative history or its subsequent administrative interpretation supports petitioner's claim that it is within the province of a court or jury to determine in each case the sharing of royalties under section 202. Because the lower courts correctly decided the issue presented, this Court should deny the petition.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari to the United States Court of Appeals for the Federal Circuit should be denied.

Dated: New York, New York
March 5, 1993

Steven B. Rosenfeld
1285 Avenue of the Americas
New York, New York 10019-6064
(212) 373-3000

Counsel of Record for Respondent

Of Counsel:

Catherine J. Ross
Kathleen M. Walker

PAUL, WEISS, RIFKIND, WHARTON & GARRISON

APPENDIX—COMPLAINT OF PLAINTIFFS DR. ERICH PLATZER, DR. KARL WELTE AND DR. ROLAND MERTELSMANN DATED SEPTEMBER 30, 1991

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

----------x

DR. ERICH PLATZER, DR. KARL WELTE and DR. ROLAND MERTELSMANN,

Plaintiffs,

-against-

SLOAN-KETTERING INSTITUTE FOR CANCER RESEARCH,

Defendant.

91 Civ. 6578 (JSM)

COMPLAINT

----------x

Plaintiffs, Dr. Erich Platzer, Dr. Karl Welte, and Dr. Roland Mertelsmann, by their attorneys, Gold, Farrell & Marks, for their complaint against defendant Sloan-Kettering Institute for Cancer Research ("SKI"), allege:

Jurisdiction and Venue

1. Plaintiff Dr. Erich Platzer is a citizen and resident of the Federal Republic of Germany.

2. Plaintiff Dr. Karl Welte is a citizen and resident of the Federal Republic of Germany.

3. Plaintiff Dr. Roland Mertelsmann is a citizen of the United States and is both a resident of the City, State and Southern District of New York, and of the Federal Republic of Germany.

4. Upon information and belief, defendant SKI is a not-for-profit corporation, organized under the laws of the State of New York with its principal place of business located within the City, State and Southern District of New York.

5. This Court has jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a) because the claims arise under the patent laws and policies of the United States and require construction and interpretation of such laws. This Court has jurisdiction of other claims under principles of pendent jurisdiction.

6. Venue in this Court is proper on the ground that defendant is located within the City, State and Southern District of New York, and the claims have arisen therein.

The Parties And Their Dispute

7. This action involves the rights of three research physicians to share the royalties flowing as a result of their federally funded inventive research, conducted at SKI. The subject matter of their research was hemopoietins, the hormones which induce production of various kinds of blood cells in human beings. Several years ago the medical research community recognized that the production of these hormones "may effect a revolution in medicine as profound as the introduction of antibiotics half a century ago." (Golde & Gasson, *Hormones That Stimulate the Growth of Blood Cells*, *Scientific American*, July 1988, p. 62).

8. Plaintiffs' research at SKI was funded with grants provided by the United States Government. The salaries of Drs. Platzer and Welte while at SKI were, in part, paid with grants provided by the Federal Republic of Germany. Incurring virtually no expenses, SKI has already realized $50 million in royalties from the fruits of plaintiffs' research, and over the next several years SKI is likely to realize hundreds of millions of dollars more in further royalties.

9. Despite federal patent law requirements that these sums be shared with plaintiffs, SKI has paid each plaintiff only approximately 1%

of the sums it has received, and has refused to pay larger portions to plaintiffs from future royalties to be received.

10. Plaintiffs' specific research at SKI concerned granulocyte colony stimulating factor ("G-CSF"). G-CSF stimulates the proliferation and differentiation, and thereby the production, of neutrophilic granulocytes from bone marrow progenitor cells. Neutrophils are white blood cells essential to the body's immune system and defense mechanisms against infection. Plaintiffs' revolutionary invention was the underlying discovery and process necessary to permit the manufacture, using recombinant technology, of G-CSF, which is now prescribed and marketed in the United States (under the brand name "Neupogen") and throughout much of the world. G-CSF is used in conjunction with chemotherapy administered to cancer patients. Such treatments often cause the destruction of neutrophil production, leading to neutropenia, which in turn exposes patients to increased risk of life-threatening infections. Because G-CSF stimulates the production of neutrophils, it thereby materially reduces the deleterious side-effects of such treatment, and enables patients to tolerate therapeutic dosages which otherwise might have to be reduced due to toxicity. G-CSF will likely have many other significant medical applications for the prevention and treatment of neutropenia, including bone marrow transplants, burn treatment, concomitant AIDS therapy and treatment of other forms of chronic neutropenia.

11. The financial impact of plaintiffs' invention is equally impressive. It has been estimated that sales of G-CSF drugs will be at least $600 million annually over the next five years. SKI has already received an advance of $50 million for its rights to royalties for domestic sales of G-CSF. SKI has virtually no expenses to pay from these funds since the G-CSF research was financed with government funds. Nevertheless, SKI has paid to each of the plaintiffs only approximately 1% of these proceeds.

12. Plaintiffs bring this action for judgment declaring that pursuant to statute, statutorily required contractual provisions which are a part of the government funding agreements, the agreements between the parties and common law principles, plaintiffs are three of the five

inventors of G-CSF, that the inventors are together entitled to receive and share 50% of G-CSF royalties as and when received by defendant, or a fair and reasonable portion of all royalties, and for judgment against defendant allocating royalties previously received, calculated in such manner.

Governing Laws

13. The purpose of the United States patent laws is "To promote the progress of science and useful arts, by securing for limited times to . . . inventors the exclusive right to their . . . discoveries." (U.S. Constitution, Article I, Section 8, Clause 8.)

14. In furtherance of this purpose, the federal government has, for many years, funded research at non-profit institutions, such as SKI. In 1980, in an effort to stimulate inventions arising from federally supported research and development, Congress fundamentally altered United States patent policy to encourage nonprofit organizations to obtain patents to inventions and to commercially market such inventions for profit. (35 U.S.C. § 200 *et seq.*, Pub. L. 96-517, 94 Stat. 3019, effective July 1, 1981).

15. The 1980 legislation grants non-profit organizations the exclusive title to inventions developed through federally funded research and development, and allows them to freely license such inventions. In addition, the statute provides, in pertinent part:

> Each funding agreement with a . . . nonprofit organization shall contain appropriate provisions to effectuate the following: . . . (B) a requirement that the contractor share royalties with the inventor. . . .

35 U.S.C. § 202(c)(7)(B) ("§ 202(c)(7)(B)").

16. The purpose of § 202(c)(7)(B) is to ensure that inventors are fairly compensated for their labors, and that they are thereby given

the incentive to fulfill the Constitutional and statutory intent of encouraging new inventions and technology for the public welfare.

Facts

17. Dr. Erich Platzer was educated in Bavaria, Germany and acquired a diverse background in physics and mathematics before undertaking his medical studies. While pursuing his doctoral studies, Dr. Platzer became involved in clinical immunology at the Department of Immunology at Erlangen, Germany, where he earned his medical degree. Upon completion of his medical studies, Dr. Platzer continued his research in the immune systems of cancer patients.

18. Dr. Karl Welte earned his medical degree in West Berlin, Germany. Following a residency in the Department of Pediatric Hematology and Oncology at the Children's Hospital, West Berlin, Dr. Welte became a research and clinical fellow in the areas of molecular biology, pediatric hematology and oncology. Dr. Welte's research included the purification and the biochemical and immunological characterization of viral enzymes from human cancer tissues and tumors.

19. Dr. Roland Mertelsmann earned his medical degree from the University of Hamburg, Germany where he remained as a resident in Internal Medicine, Medical Oncology and Hematology. He also served as Assistant Professor of Medicine and earned his Ph.D. at the University of Hamburg. From 1976 through 1984 he conducted research at SKI, and was an Attending Physician at Memorial Sloan-Kettering Cancer Center ("MSKCC") and a Professor of Medicine at Cornell University Medical College. He conducted and supervised research in Oncology and Hematology. He is presently a Professor of Medicine at Freiburg University Medical Center, Freiburg, Germany.

20. Beginning in 1981, Drs. Platzer and Welte conducted research at SKI. Both were supported by research grants funded by the Federal Republic of Germany. Dr. Platzer's research was initially focused on inhibitory molecules of hematopoiesis, in collaboration with Dr. Hal Broxmeyer. Dr. Welte, working in collaboration with Dr. Mertelsmann, succeeded in purifying to homogeneity the human

T-cell growth factor now known as Interleukin-2. Dr. Platzer left SKI in 1984 and returned to Germany. He presently is a Privatdozent of Internal Medicine, Attending Physician and Senior Researcher at the University of Erlangen. Dr. Welte remained at SKI until 1987 when he returned to Germany, and between 1985 and 1987, he was head of the Laboratory of Cytokine Biology. He is presently a Professor of Pediatrics in Hannover, Germany.

21. In or about January 1982, Dr. Platzer began focusing his research on certain colony stimulating factors, naturally produced in humans, which induce the production of various types of blood cells in bone marrow. His goal was to purify such substances for amino acid sequencing, in order to allow isolation of encoding C-DNA clones for commercial production. Dr. Platzer hypothesized that a collaboration with Dr. Welte held promise of furthering such a project, and Drs. Platzer and Welte thereupon decided to pursue such research together.

22. In furtherance of such purpose, from 1982 to 1984, Drs. Platzer and Welte conducted their research together at SKI, often working in collaboration with Drs. Mertelsmann, Gabrilove and Moore. By fall 1983, they had successfully purified G-CSF to the extent that it could be amino acid sequenced.

23. Subsequent repetitive application of this purification procedure by plaintiffs ultimately enabled the cloning of encoding C-DNA clones, which resulted in commercial production of G-CSF.

24. Dr. Mertelsmann was head of the Laboratory of Molecular Hematology at SKI at which Dr. Welte performed research. Dr. Mertelsmann collaborated with Dr. Welte and contributed to the purification of G-CSF.

25. Dr. Janice Gabrilove, then a clinical fellow at MSKCC, performed research in the laboratory in which Dr. Platzer worked. She contributed to the purification of G-CSF. Dr. Gabrilove continues to be employed by MSKCC and/or SKI.

26. Dr. Malcolm A. S. Moore was head of the Department of Developmental Hematopoiesis of SKI at which Drs. Platzer, Welte and Gabrilove performed research. Dr. Moore contributed to the purification of G-CSF. Dr. Moore continues to be employed by MSKCC and/or SKI.

27. Drs. Platzer, Welte, Mertelsmann, Gabrilove, and Moore are inventors of G-CSF for all relevant purposes herein.

28. The aforesaid research conducted at SKI which led to the purification of G-CSF was funded and supported by the United States pursuant to funding agreements. At all times relevant herein, the terms and conditions of such government funding agreements included the statutory "requirement that [SKI] share royalties with the inventor", required by § 202(c)(7)(B).

29. At all times relevant herein, it was a part and condition of the agreements of employment between Drs. Platzer, Welte, and Mertelsmann and SKI, and a covenant thereof, that the parties would abide by all government statutes and regulations applicable to government financed research, including the requirements that proprietary rights to inventions would be owned by SKI and assigned to it by Drs. Platzer, Welte, and Mertelsmann, and that SKI would share royalties with Drs. Platzer, Welte, and Mertelsmann in accordance with § 202(c)(7)(B).

30. Upon information and belief, on or about February 12, 1986, SKI granted an exclusive worldwide license for G-CSF to Amgen, Inc., a Delaware corporation in the pharmaceutical business with principal offices located in Thousand Oaks, California. Under the terms of such licensing agreement, SKI would receive percentages of Amgen's net sales. In addition, SKI and Amgen, Inc. agreed that the licensing agreement would be subject to applicable federal government patent statutes and regulations.

31. At a time unknown to plaintiffs, and without giving plaintiffs any notice thereof, upon information and belief, SKI unilaterally adopted a policy of distributing to inventors a portion of the

annual gross proceeds derived from inventions and discoveries ("SKI Policy"). The SKI Policy provides for distribution to inventors of the following proportion of the annual gross proceeds of their inventions, as follows:

$0–$50,000	25%
$50,000–$150,000	15%
$150,000–$300,000	10%
over $300,000	5%

32. On or about November 26, 1990, SKI wrote to plaintiffs to advise them that the licensing agreement with Amgen, Inc. had been amended and that SKI was then receiving a $50 million fee in exchange for its rights to royalties for U.S. sales of plaintiffs' invention, and would receive an additional $10 million after three years of United States sales without competition, and an additional $15 million after five years of U.S. sales without competition. SKI informed plaintiffs that it would receive additional royalties from domestic sales, and royalties from foreign sales as originally planned.

33. Purporting to apply the SKI Policy, SKI advised plaintiffs that they would each receive $505,490, representing approximately 1% of the amount received by SKI. The said sum was received by each plaintiff shortly thereafter.

34. The meaning and intent of § 202(c)(7)(B) is that the "contractor" (SKI) is to share royalties *equally* with the "inventor" (plaintiffs), *i.e.*, the inventors would together receive a total of 50% of all royalties received by SKI.

35. Alternatively, the meaning and intent of § 202(c)(7)(B) is that the "contractor" is to share royalties on a fair and equitable basis with the inventors. Sharing royalties on a fair and equitable basis would also require that SKI pay 50% of all royalties received with the inventors.

36. Many non-profit research institutions have adopted policies of allocating portions of royalties to inventors, purporting to comply with § 202(c)(7)(B). Upon information and belief, at least one preeminent American research institution has adopted plaintiffs' interpretation of § 202(c)(7)(B), and such institution pays 50% of royalties to inventors. Most other institutions have adopted policies pursuant to which they pay between 15% and 40% of royalties to inventors. Plaintiffs are unaware of any other institution which has a policy which is anywhere as parsimonious as the restrictive and overreaching policy which SKI has enforced against plaintiffs.

37. The aforesaid payments made to plaintiffs do not comply with the legal requirements of § 202(c)(7)(B), pursuant to which SKI is required to have been paid the inventors 50%, or a fair or reasonable portion, of the royalties received, which would amount to $25 million.

38. The aforesaid payments made to plaintiffs do not comply with the SKI Policy, which SKI claims is applicable. That policy requires that inventors' shares are to be calculated upon "annual gross proceeds derived from an invention or discovery", not merely upon receipts by SKI. Upon information and belief, such annual gross proceeds will be in excess of $600 million annually worldwide over five years. Applying the SKI Policy, the inventors would together be entitled to receive a total of approximately $150 million over such five year period.

39. An actual controversy exists between plaintiffs and defendant within the meaning of 28 U.S.C. § 2201(a).

FIRST CLAIM FOR RELIEF
(Statutory Right of Action)

40. Plaintiffs repeat and reallege paragraphs 1-37 and 39 hereof.

41. Pursuant to § 202(c)(7)(B), SKI as a recipient of federal funding, is obligated to the inventors to share royalties with them, and is liable to them for breaching such statutory obligation.

42. SKI has breached its statutory obligation requiring it to share royalties with inventors by failing to pay plaintiffs and the other inventors a total of 50%, or a fair and a reasonable portion, of the royalties SKI has received and expects to receive from the commercial exploitation of G-CSF.

43. Plaintiffs have been damaged in an amount to be proved at trial, but not less than $13.5 million on account of past royalties. In addition, they are entitled to a declaration of their rights with respect to future royalties, and an award of reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

SECOND CLAIM FOR RELIEF
(Third Party Beneficiary)

44. Plaintiffs repeat and reallege paragraphs 1-37 and 39 hereof.

45. Plaintiffs are third party beneficiaries of the statutorily mandated contractual provision contained in § 202(c)(7)(B) requiring SKI, as a recipient of federal funding, to share royalties with the inventors.

46. SKI has breached this provision requiring it to share royalties with inventors by failing to pay plaintiffs and the other inventors a total of 50%, or a fair and a reasonable portion, of the royalties SKI has received and expects to receive from the commercial exploitation of G-CSF.

47. Plaintiffs have been damaged in an amount to be proved at trial, but not less than $13.5 million on account of past royalties. In addition, they are entitled to a declaration of their rights with respect to future royalties, and an award of reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

THIRD CLAIM FOR RELIEF
(Breach of Contract)

48. Plaintiffs repeat and reallege paragraphs 1-37 and 39 hereof.

49. The statutorily mandated contractual provision contained in § 202(c)(7)(B) requiring SKI, as a recipient of federal funding, to share royalties with the inventors was a part and condition of the agreements of employment between plaintiffs and SKI, and a covenant thereof.

50. SKI has breached this provision requiring it to share royalties with inventors by failing to pay plaintiffs and the other inventor a total of 50%, or a fair and a reasonable portion, of the royalties SKI has received and expects to receive from the commercial exploitation of G-CSF.

51. Plaintiffs have been damaged in an amount to be proved at trial, but not less than $13.5 million on account of past royalties. In addition, they are entitled to a declaration of their rights with respect to future royalties, and an award of reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

FOURTH CLAIM FOR RELIEF
(Breach of Contract—Alternative Pleading)

52. If the Court determines that the SKI Policy is binding upon the parties hereto, as a part and condition of the agreements of employment between plaintiffs and SKI, then plaintiffs are entitled to the relief set forth in this claim.

53. Plaintiffs repeat and reallege paragraphs 1-33 and 38-39 hereof.

54. Plaintiffs are entitled to receive sums calculated in accordance with the SKI Policy, but based upon annual gross proceeds

received by any person, based upon past and future sales, not merely based upon royalties received by SKI from Amgen, Inc.

55. SKI has breached this contractual obligation to plaintiffs by calculating the percentages payable to inventors under the SKI Policy only on the basis of royalties received by SKI from Amgen, Inc., rather than based upon annual gross proceeds received by any person as a result of sales of G-CSF, as is required under the SKI Policy.

56. Plaintiffs have been damaged in an amount to be proved at trial which plaintiffs presently believe to be approximately $18 million. In addition, they are entitled to a declaration of their rights with respect to future royalties, and an award of reasonable attorneys' fees.

FIFTH CLAIM FOR RELIEF
(Unjust Enrichment)

57. Plaintiffs repeat and reallege paragraphs 1-39, 41-43, 45-47, 49-51 and 54-56 hereof.

58. SKI has received and will continue to receive enormous financial benefits from sales of G-CSF throughout the world, solely as a result of plaintiffs' invention.

59. Plaintiffs are entitled to an award of damages in an amount to be proved at trial, but not less than their fair and reasonable inventors' share of all past and future royalties.

WHEREFORE, plaintiffs demand judgment, as follows:

A. On the first, second and third claims for relief, declaring the rights of the parties, and for judgment against defendant in an amount to be proved at trial based upon past receipts of royalties on account of G-CSF, in the amount of at least $13.5 million, together with attorneys' fees.

B. Alternatively, on the fourth claim for relief, declaring the rights of the parties and for judgment against defendant in an amount to be proved at trial based upon annual gross proceeds received by any person from sales of G-CSF, in the amount of at least $18 million, together with attorneys fees.

C. On the fifth claim for relief, declaring the rights of the parties and for judgment against defendant in an amount to be proved at trial.

D. On all claims for relief, for attorneys fees, interest, costs and disbursements and such other and further relief as the court deems just and proper.

Dated: New York, New York
September 30, 1991

GOLD, FARRELL & MARKS

By: /s/
Martin R. Gold, 6528
A Member of the Firm

41 Madison Avenue
New York, New York 10010
(212) 481-1700

Attorneys for Plaintiffs
Dr. Erich Platzer
Dr. Karl Welte
Dr. Roland Mertelsmann

Supreme Court, U.S.
FILED
MAR 15 1993
OFFICE OF THE CLERK

No. 92-1345

In The

Supreme Court of the United States

October Term, 1992

DR. ERICH PLATZER, DR. KARL WELTE AND DR. ROLAND MERTELSMANN,

Petitioners,

vs.

SLOAN-KETTERING INSTITUTE FOR CANCER RESEARCH,

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

REPLY BRIEF OF PETITIONERS

MARTIN R. GOLD
Counsel of Record
ROBERT P. MULVEY
GOLD, FARRELL & MARKS
Attorneys for Petitioners
Forty-One Madison Avenue
New York, New York 10010
(212) 481-1700

3230
Lutz Appellate Services, inc.
(800) 3 APPEAL • (800) 5 APPEAL • (800) BRIEF 21

TABLE OF CONTENTS

	Page
Reply Statement of the Case	2
A. SKI's Royalty-Sharing Policy Was Unilaterally Adopted And Imposed	2
B. SKI's Royalty-Sharing Practices Do Not Compare With Those Of Other Institutions	3
Reasons For Granting The Writ	4
I. The Petition Raises Important First Impression Issues Of Statutory Construction.	4
II. The Decisions Of The Lower Courts Violate Canons Of Statutory Construction.	5
Conclusion	7

TABLE OF CITATIONS

Cases Cited:

American Federation of Musicians v. Wittstein, 379 U.S. 171 (1964)	4
Commissioner of Internal Revenue v. Brown, 380 U.S. 563 (1965)	6
DeSylva v. Ballentine, 351 U.S. 570 (1956)	4
Federal Power Commission v. Sierra Pacific Power Co., 350 U.S. 348 (1956)	4

Contents

Page

Moskal v. United States, 498 U.S. 103 (1990) 6

N.L.R.B. v. District 50, United Mine Workers of America, 355 U.S. 453 (1958) 4

Negonsott v. Samuels, 61 U.S.L.W. 4185 (U.S. Feb. 24, 1993) 6

Rathbun v. United States, 355 U.S. 107 (1957) 6

Rosado v. Wyman, 397 U.S. 397 (1970) 6

State of Wisconsin v. J.C. Penney Co., 311 U.S. 435 (1940) 6

United Gas Pipe Line Co. v. Mobile Gas Service Corp., 350 U.S. 332 (1956) 4

United States v. American Trucking Ass'ns, 310 U.S. 534 (1940) 6

United States v. Menasche, 348 U.S. 528 (1955) 6

United States v. Nordic Village, Inc., 112 S. Ct. 1011 (1992) 6

Zuber v. Allen, 396 U.S. 168 (1969) 7

Statutes and Regulations Cited:

35 U.S.C. § 202(c) 6

Contents

	Page
35 U.S.C. § 202(c)(7)(B)	2
HHS Regulation, 46 F.R. 62548 (1981)	3
Legislative History Cited:	
S. Rep. No. 480, 96th Cong., 1st Sess. (1979)	6
Other Authority Cited:	
Black's Law Dictionary (6th Ed.)	6

No. 92-1345

In The

Supreme Court of the United States

October Term, 1992

DR. ERICH PLATZER, DR. KARL WELTE and DR. ROLAND MERTELSMANN,

Petitioners,

vs.

SLOAN-KETTERING INSTITUTE FOR CANCER RESEARCH,

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

REPLY BRIEF OF PETITIONERS

Petitioners, Dr. Erich Platzer, Dr. Karl Welte and Dr. Roland Mertelsmann, respectfully submit this Reply Brief in support of their Petition for a writ of certiorari to the United States Court of Appeals for the Federal Circuit.[1]

1. References to the Brief in Opposition are cited as "Opp. __", and to its Appendix as "Opp. __a".

Respondent, Sloan-Kettering Institute for Cancer Research, Inc. ("SKI"), does not dispute that this is the first case requiring interpretation of a major piece of legislation enacted to stimulate the American economy by encouraging invention and its commercial application, or that the lower courts have sanctioned a mechanism that undermines the statutory framework and thereby frustrates its purpose.

In an effort to avoid review by this Court, however, SKI has distorted important facts which are not in dispute, and has drawn incorrect conclusions as to the purpose and intent of the statute by perverting the plain statutory language and ignoring authoritative statements of congressional intent.

REPLY STATEMENT OF THE CASE

A. SKI's Royalty-Sharing Policy Was Unilaterally Adopted And Imposed.

In order to ensure that royalty-sharing arrangements with inventors are substantively reviewed and approved by government agencies, the relevant section of the Bayh-Dole Act, 35 U.S.C. § 202(c)(7)(B), explicitly provides that funding agreements between such agencies and non-profit institutions must themselves contain the required provision. Although SKI knows quite well that the agreements in this case *did not* contain the required provision, and that no government agency reviewed its unilaterally-adopted policy, it would like to leave a contrary impression with this Court.

At an earlier stage of this case, when SKI was pursuing a different tact, it disclosed to the district court in an affidavit of its attorney, Steven B. Rosenfeld, Esq., that prior to the commencement of litigation, SKI had voluntarily produced documents to Petitioners, and that among such documents was a 1969 Institutional Patent Agreement between SKI and the

Department of Health, Education and Welfare, which Mr. Rosenfeld attached to his affidavit and acknowledged was "the only government 'funding agreement' covering the research done by [Petitioners] while they were employed at [SKI]".[2] In that agreement, which predated the Bayh-Dole Act by many years, the only provision governing royalty sharing with inventors is a 15% *limitation* on the amount which could be shared with inventors. That provision was expressly repealed and deleted from all such agreements by regulation promulgated in 1981 by the Department of Health and Human Services to bring such agreements into compliance with the Bayh-Dole Act. HHS Regulation, 46 F.R. 62548 (1981). The regulation states that its purpose is to remove the 15% limitation on royalty sharing with inventors. As Mr. Rosenfeld has admitted on behalf of SKI, no new royalty-sharing provision was thereafter incorporated in any funding agreement. Accordingly, it is most disingenuous for SKI to argue to this Court that because the complaint alleged that the required provision was a part of the funding agreements, "either expressly or by operation of law" (Opp. 2), that the provision was reviewed by a government agency; no such review took place.

B. SKI's Royalty-Sharing Practices Do Not Compare With Those Of Other Institutions.

In paragraph 36 of their complaint (Opp. 9a), which must be accepted as true at the pleading stage, Petitioners alleged that research institutions throughout the United States have adopted royalty-sharing policies in compliance with the statute. They alleged that they were "unaware of any other institution which has a policy which is anywhere as parsimonious as the restrictive and overreaching policy which SKI has enforced against [Petitioners]". Moreover, SKI admitted in the lower courts that its "royalty-sharing practices pursuant to its Patent Policy . . . are

---

2. Joint Appendix, Fed. Cir., 42-46.

neither the same as, nor comparable to, the practices of certain other non-profit institutions". (Joint Appendix, Fed. Cir., 285). Petitioners' survey of the practices of other institutions was submitted to the lower courts solely to amplify this undisputed allegation, and not to alter the facts. Accordingly, SKI's objection to the survey, the accuracy of which it does not contest, is quite baseless.

REASONS FOR GRANTING THE WRIT

I.

THE PETITION RAISES IMPORTANT FIRST IMPRESSION ISSUES OF STATUTORY CONSTRUCTION.

Contrary to SKI's argument, the fact that this is an important case of first impression regarding construction of a federal statute augments, rather than detracts from, the reasons for granting certiorari. *See, e.g., American Federation of Musicians v. Wittstein,* 379 U.S. 171, 175 (1964).

Moreover, this case involves the administration of a federal statute, and certiorari is often granted to ensure the proper administration of federal statutes. *See, e.g., N.L.R.B. v. District 50, United Mine Workers of America,* 355 U.S. 453, 458 (1958) (administration of National Labor Relations Act); *DeSylva v. Ballentine,* 351 U.S. 570, 572 (1956) (administration of Copyright Act); *Federal Power Commission v. Sierra Pacific Power Co.,* 350 U.S. 348, 352 (1956) (administration of Federal Power Act); *United Gas Pipe Line Co.* v. *Mobile Gas Service Corp.,* 350 U.S. 332, 337-38 (1956) (administration of Natural Gas Act).

SKI contends that because no similar case has apparently arisen since the Bayh-Dole Act became effective in 1981, this

Petition does not warrant the Court's consideration. However, SKI ignores the significant and time-consuming events likely to precede litigation under this statute. In the present case, Petitioners' research was proposed in 1981, shortly after the Bayh-Dole Act became effective, and was conducted between 1982 and 1984 (Opp. 5a-6a). Development of the resulting drug followed, and royalties were first realized in November 1990 (Opp. 7a-8a). The present case was filed in September 1991 (Opp. 13a). It is, therefore, too soon after the enactment of the Bayh-Dole Act to conclude that the present case is an isolated dispute under that statute.

If the result below is permitted to stand, however, other major institutions, which have heretofore been sharing royalties with inventors on a reasonable basis, may well conclude that such a course is neither prudent nor necessary. This would undermine the statute and lead to further litigation.

II.

THE DECISIONS OF THE LOWER COURTS VIOLATE CANONS OF STATUTORY CONSTRUCTION.

The lower courts construed the statute in a manner that fails to give meaningful effect to the royalty-sharing provision, disregarded explicit terms, and ignored legislative history demonstrating that Congress intended that the share paid to inventors must be reasonable. The decisions of the lower courts are thus contrary to this Court's precedents governing statutory construction. It is undeniable from the statutory language, the clear intent and the overall scheme of the statute, that a major purpose of the Bayh-Dole Act was to encourage inventors, and that the utilization of remainder funds by non-profit institutions for additional research was a subsidiary concern. The lower courts

failed to construe the statute in a manner consistent with this congressional intent and thus contrary to this Court's dictates. *See, e.g., Rosado v. Wyman,* 397 U.S. 397, 415 (1970); *Commissioner of Internal Revenue v. Brown,* 380 U.S. 563, 571 (1965); *Rathbun v. United States,* 355 U.S. 107, 109 (1957); *State of Wisconsin v. J.C. Penney Co.,* 311 U.S. 435, 443 (1940); *United States v. American Trucking Ass'ns,* 310 U.S. 534, 542-44 (1940).

In construing the statutory provision to allow the payment of any *de minimis* amount to inventors, the lower courts failed to give effect to certain governing terms contained in 35 U.S.C.§ 202(c), which provide that the funding agreement must be "appropriate" "to effectuate" all of the enumerated requirements, including the requirement that the non-profit institution share royalties with inventors. Contrary to SKI's unsupported statement, the word "appropriate" is fully synonymous with "reasonable." *Black's Law Dictionary* (6th Ed.). SKI, nevertheless, contends that "appropriate" only refers to "the list of terms which are to be included in the funding agreement." (Opp. 7). Even by SKI's analysis, however, such terms include the royalty-sharing provision, which must be sufficiently "appropriate" "to effectuate" the intent to provide incentives to inventors. The lower courts' reading of the provision is contrary to this Court's holdings that courts must give effect to every word in a statute because of the presumption that Congress uses no superfluous language. *See, e.g., Negonsott v. Samuels,* 61 U.S.L.W. 4185, 4187 (U.S. Feb. 24, 1993); *United States v. Nordic Village, Inc.,* __ U.S. __, 112 S. Ct. 1011, 1015 (1992); *Moskal v. United States,* 498 U.S. 103, 109-10 (1990); *United States v. Menasche,* 348 U.S. 528, 538-39 (1955).

SKI repeatedly quotes the statement in the Senate Report, S. Rep. No. 480, 96th Cong., 1st Sess. (1979) at 33, that Congress did not intend to establish sharing ratios, although Petitioners do not dispute this point. Rather, Petitioners contend that the royalty share must be reasonable to further the statutory purpose. Neither SKI nor the lower courts address the immediately preceding sentence in

the same Senate Report that the statute "gives special recognition to the equity of inventors." *Id.*

Contrary to SKI's arguments, the legislative history confirms what appears obvious from the face of the statute, that Congress intended a reasonable share for inventors. Congress heard testimony from the draftsman of the statute, Norman J. Latker, that the purpose of the statute was to establish "a reasonable share to inventors." (Joint Appendix, Fed. Cir., 183).

The lower courts disregarded Mr. Latker's testimony, although, under this Court's holdings, the views of a statute's draftsman, when they have been communicated to Congress, are a significant source of congressional intent. *See, e.g., Zuber v. Allen,* 396 U.S. 168, 192 (1969).

CONCLUSION

Petitioners respectfully pray that this Court grant a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit.

Respectfully submitted,

MARTIN R. GOLD
Counsel of Record
ROBERT P. MULVEY
GOLD, FARRELL & MARKS
Attorneys for Petitioners
41 Madison Avenue
New York, New York 10010
(212) 481-1700

Dated: New York, New York
March 15, 1993